

Remarks

No further amendments are presented.

Claims 62, 63, 69, 71, 72, 82, and 85-95 remain in the application.

Claims 63, 69, 71, 72, 82, and 85-95 have been held to be withdrawn from consideration.

Reexamination and reconsideration of the application are respectfully requested.

ARGUMENTS

2. The Non-Elected Process Claims Should be Rejoined After the Product Claims Have Been Allowed

Applicant respectfully submits that once the elected Claims to the rice plants have been allowed, the non-elected Claims directed to processes for making and using the rice plants should then be rejoined and examined in the same application. In particular, the Office's attention is respectfully directed to M.P.E.P. § 821.04, which provides for rejoinder of process Claims in such a case.

Note particularly that rejoinder under M.P.E.P. § 821.04 does not depend upon whether the original election was made with or without traverse.

Applicant interprets the Office's June 3, 2004, October 6, 2005, and June 23, 2006 comments on this point as agreeing with Applicant's position in principle.

7. The Written Description Rejection

The Office repeated the written description rejection of Claim 62, despite the amendments that were previously made to Claim 62 to include an extensive "fingerprint" characterization of the claimed rice plants. Claim 62 now includes the following limitations:

(d) the rice plant expresses a mutant acetohydroxyacid synthase whose enzymatic activity is directly resistant to normally-inhibitory levels of a herbicidally-effective imidazolinone;

(e) the rice plant is resistant to each of the following imidazolinone herbicides, at levels of the imidazolinone herbicides that would normally inhibit the growth of a rice plant: imazethapyr, imazapic, imazaquin, imazamox, and imazapyr;

(f) the rice plant is resistant to each of the following sulfonylurea herbicides, at levels of the sulfonylurea herbicides that would normally inhibit the growth of a rice plant: nicosulfuron, metsulfuron methyl, thifensulfuron methyl, and tribenuron methyl; and

(g) the rice plant is sensitive to each of the following sulfonylurea herbicides, at levels of the sulfonylurea herbicides that would normally inhibit the growth of a rice plant: sulfometuron methyl, chlorimuron ethyl, and rimsulfuron.

The written description requirement of section 112 requires that the specification “reasonably” convey that the inventor was in possession of the claimed invention. (June 23, 2006 Office Action, p. 3, first full paragraph.) Section 112 does not require that all aspects of a novel composition must be fully and completely characterized before a patent application may be filed.

The carryover paragraph on the top of page 5 of the October 6, 2005 Office Action describes another purpose of the written description requirement: to give innocent third parties notice of what the claimed invention is. The “fingerprint” definition satisfies this goal. A third party may readily determine whether the traits of any given rice plants are consistent or inconsistent with the “fingerprint” of amended Claim 62. Section 112 does not require more.

The June 23, 2006 Office Action gave five grounds for objecting to the amended, “fingerprint” limitations of Claim 62. Each of the Office’s five grounds of objection is addressed below. These arguments are given labels (a) through (e) for convenience of reference. (These labels do not appear in the Office Action itself.)

(a) “The ‘fingerprint’ description, as argued by Applicant, does not describe what the specific structural feature, the claimed herbicide-resistant rice plant has.” (June 23, 2006 Office Action, p. 3)

A “fingerprint” description is an accepted manner to claim a composition that may have only been partially characterized as of the filing date. In the sentence bridging pages 4-5 of the earlier, October 6, 2005 Office Action, the Office acknowledged that the “written description requirement for a claimed genus may be satisfied” by, among other possibilities, “disclosure of relevant, identifying characteristics, i.e. structure or other physical and/or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics”

Amended Claim 62 does exactly that. It recites a combination of identifying characteristics, specific properties that characterize the claimed rice plants, including the following properties:

- expression of a mutant, herbicide-resistant AHAS enzyme;
- resistance to five specified imidazolinone herbicides;
- resistance to four specified sulfonylurea herbicides; and
- sensitivity to three specified sulfonylurea herbicides.

Particularly note that amended Claim 62 states that the rice plant is sensitive to three specified sulfonylurea herbicides (part (g)). Claim 62 does not attempt to claim any and all herbicide-resistant rice plants. Rather, amended Claim 62 defines a “fingerprint” of herbicide-response characteristics: the rice plant of Claim 62 is resistant to five specified imidazolinones; it is resistant to four specified sulfonylureas; and it is sensitive to three specified sulfonylureas. Additionally, the rice plant expresses a resistant AHAS enzyme.

This method of claiming, defining a “fingerprint” for a composition of matter that has not been fully characterized, is expressly permitted by M.P.E.P. § 2173.05(t), which says in part (citations omitted): “A claim to a chemical compound is not indefinite merely because a structure is not presented A compound of

unknown structure may be claimed by a combination of physical and chemical characteristics. A compound may also be claimed in terms of the process by which it is made without raising an issue of indefiniteness.”

A complete structure is not required in order to claim a composition. “Fingerprint” claiming is expressly permitted by the M.P.E.P. The Office is in error in suggesting that a composition may not be claimed without knowledge of the complete structure.

(b) “There could be multiple mutations in a rice AHAS gene that would lead to the ‘fingerprint’ herbicide resistance” (June 23, 2006 Office Action, pp. 3-4).

The Office’s assertion is highly speculative. Given the level of detail that is provided in the “fingerprint” definition, the Office’s assertion is in all likelihood incorrect (aside from the trivial case of “synonymous” mutations).

It is undoubtedly true that different mutations in the AHAS molecule can lead to herbicide resistance. However, different mutations will result in different AHAS molecules, having different properties. Statistically, the vast majority of all possible mutations will lead to non-functional molecules, or to molecules that are functional but that remain susceptible to herbicide. A relatively small percentage of all possible mutations will result in AHAS molecules that are both functional and resistant to herbicide.

Each of this handful of mutant molecules will be chemically different. Each of these distinct molecules will have different chemical properties. Some will be resistant to herbicide A, but not to herbicide B. Some will be resistant to herbicide B, but not to herbicide A. Some will be susceptible to both A and B, but resistant to herbicide C. And so on.

The different mutant molecules will have different degrees of susceptibility and resistance to different herbicides. Merely observing that the molecule is resistant to herbicide A may not uniquely define it. Several mutant molecules may be resistant to A. Saying that it is also resistant to B narrows the group of possibilities. Then observing that it is susceptible to C narrows the possibilities even

further. And so forth. The greater the number of herbicides for which resistance or susceptibility has been characterized, the smaller becomes the pool of potential mutant molecules that would share the same traits. Eventually, when the molecule's susceptibility and resistance to a sufficient number of herbicides has been characterized, it becomes reasonable to conclude, it becomes more probable than not, that the observed pattern of herbicide resistance and susceptibility uniquely defines a single mutant molecule. The burden of proof shifts to one who would assert that there could be more than one mutant molecule having the same spectrum of traits.

Claim 62, as amended, requires that the rice plant:

- (1) express a mutant acetohydroxyacid synthase whose enzymatic activity is directly resistant to normally-inhibitory levels of a herbicidally-effective imidazolinone
- (2) is resistant to imazethapyr (an imidazolinone)
- (3) is resistant to imazapic (an imidazolinone)
- (4) is resistant to imazaquin (an imidazolinone)
- (5) is resistant to imazamox (an imidazolinone)
- (6) is resistant to imazapyr (an imidazolinone)
- (7) is resistant to nicosulfuron (a sulfonylurea)
- (8) is resistant to metsulfuron methyl (a sulfonylurea)
- (9) is resistant to thifensulfuron methyl (a sulfonylurea)

(10) is resistant to tribenuron methyl (a sulfonylurea)

(11) is sensitive to sulfometuron methyl (a sulfonylurea)

(12) is sensitive to chlorimuron ethyl (a sulfonylurea)

(13) is sensitive to rimsulfuron (a sulfonylurea)

At some point there will be a sufficient number of defining characteristics in a “fingerprint” to persuade a person of ordinary skill in the art that a particular molecule has been uniquely defined. Indeed, were that not the case, there would be little reason for the M.P.E.P. to allow fingerprint claims. If only a small number of identifying characteristics had been presented, then a closer case might have been presented. But any cutoff has clearly been exceeded here. A person of ordinary skill in the art would accept this “fingerprint” as uniquely defining a single mutant rice AHAS molecule. A contrary conclusion is unreasonable with so many defining traits given as express Claim limitations.

Note particularly that these herbicide-response traits include sensitivity to certain sulfonylurea herbicides, and resistance to others of the same sulfonylurea class. A person of ordinary skill in the art would be persuaded that this spectrum of resistance and sensitivity uniquely defines a specific mutant molecule.

(c) “[T]he description in the instant specification fails to put the public on notice as to what would be infringing” (June 23, 2006 Office Action, p. 4)

A third party may readily determine whether the traits of any given rice plants are consistent or inconsistent with the “fingerprint” of amended Claim 62. If the traits match the “fingerprint,” for the reasons just given it is only reasonable to conclude that the same mutant AHAS molecule is in fact present.

Or, viewed from a different perspective, both this objection and the objection discussed in part (b) above would appear to apply indiscriminately to any claim that

is written in “fingerprint” format. There appears to be nothing in these two grounds of objection that would not apply equally to any “fingerprint” claim at all, not just to Claim 62 of the present application. One could always speculate on the possibility that some different composition might exist that would also share the same “fingerprint” characteristics (objection (b)); or that a “fingerprint” claim does not provide adequate notice concerning what would infringe (objection (c)).

Yet M.P.E.P. § 2173.05(t) expressly permits the “fingerprint” claiming format: “A compound of unknown structure may be claimed by a combination of physical and chemical characteristics.” The “fingerprint” claim format, just as the product-by-process claiming format, represents a practical, workable accommodation that is accepted under United States in the patent law. While it might be desirable if all patented inventions could be fully characterized and precisely defined, completely free from the slightest imaginable ambiguity, before the filing date of the patent application, real-world considerations do not always grant this luxury. The “fingerprint” and “product-by-process” claiming formats strike a pragmatic balance: The Inventor is allowed the benefits of what he has discovered, even if the discovery may not have yet been fully characterized, provided that the invention is defined with reasonable precision, as well as the available data permit.

(d) “See, MPEP § 2163 which states that the claimed invention as a whole may not be adequately described where an invention is described solely in terms of a method of its making coupled with its function and there is no described or art-recognized correlation or relationship between the structure of the invention and its function.” (June 23, 2006 Office Action, p. 4)

M.P.E.P. § 2163, read in its entirety, supports the conclusion that Claim 62 has a sufficient written description. Other portions of M.P.E.P. § 2163 that are actually more relevant to Claim 62 will be discussed below. But first, the portion quoted in the Office Action will be briefly addressed.

M.P.E.P. § 2163, which provides guidelines for examining written description, occupies a little over 13 full pages of text in the printed version of the M.P.E.P. All

relevant portions of the § 2163 guidelines should be reviewed and considered carefully, not just a single sentence taken from these 13 pages in isolation.

However, even if one were to consider just the single statement selected by the Office out of context, it still would not support the Office's conclusion. First, note that the quoted statement does not purport to announce a categorical, invariable rule. It does *not* say that a claimed invention "*is never adequately described* where the invention is described" Rather, it says that a claimed invention "*may not be* adequately described where the invention is described" (emphasis added) In other words, it is intended to alert one to a possibility that should be further considered in light of all relevant considerations; it does not purport to set forth an absolute rule. Second, note that this possibility was said to exist when "there is no described or art-recognized correlation or relationship between the structure of the invention and its function." That is simply not the case here. As those of skill in the art would appreciate, and as is taught throughout the specification, and as is implied in the language of claim 62 itself, the herbicide resistance (function) of the claimed rice plants is a direct result of the inheritance of the mutant AHAS gene (structure) from the ATCC-deposited PTA-904 seeds (structure), where the plant expresses an AHAS enzyme (structure) that, itself, is directly resistant (function) to a herbicidal imidazolinone. There is a clear correlation between structure and function, so the cited sentence from M.P.E.P. § 2163 is inapplicable.

Other portions of the written description guidelines of M.P.E.P. § 2163 have a more direct bearing on the subject matter of Claim 62. Some of the more pertinent portions are discussed below. (Page numbers for citations within M.P.E.P. § 2163 are given for the printed version of the Eighth Edition, Revision 3, August 2005. All internal citations have been omitted):

Possession may be shown in a variety of ways including . . . describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. One must define a compound by

“whatever characteristics sufficiently distinguish it.” (p. 2100-173, carryover paragraph)

Generally, there is an inverse correlation between the level of skill and knowledge in the art and the specificity of disclosure necessary to satisfy the written description requirement. Information which is well known in the art need not be described in detail in the specification. (p. 2100-178, carryover paragraph)

Breeding and growing rice plants, and spraying them with herbicide to select for resistant plants, can only be described as routine. A person of skill in the art would not need detailed guidance.

An adequate written description of the invention may be shown by any description of sufficient, relevant, identifying characteristics so long as a person skilled in the art would recognize that the inventor had possession of the claimed invention. (p. 2100-178, first full paragraph)

In addition to § 2173.05(t), M.P.E.P. § 2163 also recognizes the use of the "fingerprint" claiming format.

The description need only describe in detail that which is new or not conventional. This is equally true whether the claimed invention is directed to a product or a process. (p. 2100-179, carryover paragraph)

The breeding and selection steps need not be described in detail. Note particularly that this principle applies equally to the process of breeding and selecting (which the Office does not appear to question has been adequately described) and to the product of that process (which the Office rejected as lacking a written description).

An applicant may also show that an invention is complete by disclosure of sufficiently detailed, relevant identifying characteristics which provide evidence that applicant was in possession of the claimed invention, i.e., complete or partial structure, other physical and/or chemical properties, functional characteristics when coupled with a known or disclosed correlation between function and structure, or some combination of such characteristics. (p. 2100-179, first full paragraph)

M.P.E.P. § 2163 also recognizes the use of the "fingerprint" claiming format. Note that this passage re-states, positively, what the portion cited in the Office Action had instead stated negatively. There is nothing inappropriate in defining claim limitations in functional terms, as the Office seems to have suggested. Definitions in functional terms are entirely appropriate if they are "coupled with a known or disclosed correlation between function and structure," which is clearly the case here, as previously discussed.

The same paragraph gives an example that, while not directly applicable to the present facts, nevertheless supports by analogy a finding that there is adequate written description to support the claimed invention:

One skilled in the art may be able to determine whether the gene disclosed is the same as or different from a gene isolated by another by comparing the restriction enzyme maps. In contrast, evidence that the gene could be digested with a nuclease would not normally represent a relevant characteristic since any gene would be digested with a nuclease. (p. 2100-179, first full paragraph)

The restriction enzyme map of the M.P.E.P.'s example is analogous to the characteristic herbicide resistance traits specified in Claim 62. Digestibility with nuclease in the example would be analogous to a more general trait, such as the ability of the rice seed to grow when planted under appropriate conditions. The

former characters, while perhaps not absolutely, unambiguously conclusive of identity, are compelling evidence that should be accepted in the absence of a substantial reason to conclude otherwise. Two genes that are isolated by the same protocol, and that had the same restriction enzyme maps could hypothetically still be different from one another. Yet the M.P.E.P. would accept such evidence as sufficiently compelling to satisfy the "written description" requirement. Absolute certainty is not required. Likewise, it is hypothetically possible, in principle, that some different mutation of the rice AHAS molecule could satisfy all 13 of the traits outlined in part (b) above, as required by Claim 62. But such a result is unlikely. As the example given in the M.P.E.P. shows (p. 2100-179, first full paragraph), absolute certainty is not required when an invention is defined in terms of its chemical or physical properties or functional characteristics. A rice plant that otherwise possesses all the properties defined by the limitations of Claim 62 may reasonably be presumed to have been bred from the PTA-904 herbicide resistant parent line, in the absence of evidence suggesting otherwise. Absolute certainty is not required when a written description is given in terms of chemical or physical properties or functional characteristics.

Further examples are given in p. 2100-179, second full paragraph. In these examples, the properties listed do not provide absolute certainty of identity, but would still satisfy the written description requirement: (1) an antibody with affinity to an antigen that is itself adequately defined; (2) enzyme cleavage pattern, isoelectric points of fragments, restriction enzyme maps, comparative enzymatic activity, or antibody cross-reactivity

Whether the specification shows that applicant was in possession of the claimed invention is not a single, simple determination, but rather is a factual determination reached by considering a number of factors. Factors to be considered in determining whether there is sufficient evidence of possession include the level of skill and knowledge in the art, partial structure, physical and/or chemical properties, functional characteristics alone or coupled with a

known or disclosed correlation between structure and function, and the method of making the claimed invention. Disclosure of any combination of such identifying characteristics that distinguish the claimed invention from other materials and would lead one of skill in the art to the conclusion that the applicant was in possession of the claimed species is sufficient. (p. 2100-181, first full paragraph; see also p. 2100-182, second full paragraph)

(e) "A biomolecule sequence described only by a functional characteristic, without any known or disclosed correlation between that function and the structure of the sequence, normally is not a sufficient identifying characteristic for written description purposes, even when accompanied by a method of obtaining the claimed sequence." (June 23, 2006 Office Action, p. 4)

To the extent that this is assertion is merely a restatement of argument (d), please see the discussion above. To the extent that this argument is intended to go beyond argument (d), and to focus on a "biomolecule sequence," please note that none of the limitations of Claim 62 refer to any particular "biomolecule sequence," so any such argument would be moot.

Argument (e) is either a repetition of argument (d), or it addresses a moot point.

It is respectfully submitted the written description rejection should be withdrawn.

9. The § 102(b) and § 103(a) Rejections

Claim 62 was rejected under 35 U.S.C. § 102(b) as being anticipated by Terakawa, or in the alternative under 35 U.S.C. § 103(a) as being obvious over a

proposed combination of Terakawa with two newly-cited references, Bernasconi and Hattori.

The reasons given in the May 13, 2003 Amendment and in the April 11, 2006 Request for Continued Examination for distinguishing Terakawa – reasons that will not be repeated in the interest of brevity – still fully apply. For the reasons given there, it is respectfully submitted that the Terakawa paper on its face is clearly distinguishable from the claimed inventions.

In addition to the reasons Applicant has previously presented for distinguishing Terakawa, Terakawa is not enabling prior art. Even if – for the sake of argument – one were to assume that the Examiner's assertions concerning Terakawa were otherwise correct, and that the Applicant's previous arguments were wrong (and Applicant strenuously contends just the opposite), it would nevertheless be the case that Terakawa is not enabling. The prior art rejections, which are based upon a non-enabling reference, should therefore be withdrawn.

See M.P.E.P. § 2121.03:

**2121.03 Plant Genetics - What Constitutes Enabling Prior Art
[R-3]**

**THOSE OF ORDINARY SKILL MUST BE ABLE TO GROW AND
CULTIVATE THE PLANT**

When the claims are drawn to plants, the reference, combined with knowledge in the prior art, must enable one of ordinary skill in the art to reproduce the plant. *In re LeGrice*, 301 F.2d 929, 133 USPQ 365 (CCPA 1962) (National Rose Society Annual of England and various other catalogues showed color pictures of the claimed roses and disclosed that applicant had raised the roses. The publications were published more than 1 year before applicant's filing date. The court held that the publications did not place the rose in the public domain. Information on the grafting process required to reproduce the rose was not included in the publications and such information was necessary for those of ordinary skill in the art (plant breeders) to reproduce the rose.) Compare *Ex parte Thomson*, 24 USPQ2d 1618 (Bd. Pat. App. & Inter. 1992) (Seeds were commercially available more than 1 year prior to applicant's filing date. One of ordinary skill in the art could grow the claimed cotton cultivar from the commercially available seeds. Thus, the publications describing the cotton cultivar had "enabled disclosures." The Board distinguished *In re LeGrice* by finding that the catalogue picture of the rose of *In re LeGrice* was

the only evidence in that case. There was no evidence of commercial availability in enabling form since the asexually reproduced rose could not be reproduced from seed. Therefore, the public would not have possession of the rose by its picture alone, but the public would have possession of the cotton cultivar based on the publications and the availability of the seeds.).

In *In re Elsner*, 381 F.3d 1125, 1126, 72 USPQ2d 1038, 1040 (Fed. Cir. 2004), prior to the critical date of a plant patent application, the plant had been sold in Germany and a foreign Plant Breeder's Rights (PBR) application for the same plant had been published in the Community Plant Variety Office *Official Gazette*. The court held that when (i) a publication identifies claimed the plant, (ii) a foreign sale occurs that puts one of ordinary skill in the art in possession of the plant itself, and (iii) such possession permits asexual reproduction of the plant without undue experimentation to one of ordinary skill in the art, then that combination of facts and events directly conveys the essential knowledge of the invention and constitutes a 35 U.S.C. 102(b) statutory bar. 381 F.3d at 1129, 72 USPQ2d at 1041. Although the court agreed with the Board that foreign sales may enable an otherwise non-enabling printed publication, the case was remanded for additional fact-finding in order to determine if the foreign sales of the plant were known to be accessible to the skilled artisan and if the skilled artisan could have reproduced the plant asexually after obtaining it without undue experimentation. 381 F.3d at 1131, 72 USPQ2d at 1043.<

The Office has supplied no evidence of the "commercial availability in enabling form" of Terakawa's seeds, in the words of M.P.E.P. § 2121.03.

In one of the cases cited in this section of the M.P.E.P., even foreign sales of the plant in question were not necessarily enabling: "[T]he case was remanded for additional fact-finding in order to determine if the foreign sales of the plant were known to be accessible to the skilled artisan" *A fortiori*, if there have been no sales at all, then it will generally be the case that a mere printed reference to a plant will not be enabling. The burden is on the Office to demonstrate that Terakawa's seeds are commercially available in enabling form. It is respectfully submitted that the Office will be unable to do so, as it is believed that these seeds were never commercialized at all, in enabling form or otherwise.

Terakawa is not enabling prior art. Because it is not enabling, Terakawa neither anticipates the claimed inventions, nor makes them obvious. It is

respectfully submitted that all grounds of rejection based on Terakawa should be withdrawn.

In compliance with the duty of candor to the Office, the Office is hereby notified that, with some effort, the present inventor has obtained a sample of one of Terakawa's line of seeds. This sample was not obtained commercially. So far as could be determined, the seeds are not sold commercially. Instead, the seed sample was delivered as a courtesy, following a direct personal request from one scientist to another. The process of obtaining the seeds was time-consuming. A not inconsiderable amount of red tape and quarantine procedures were required to import the seed from Japan. It is respectfully submitted that such cumbersome procedures do not satisfy the "commercial availability in enabling form" standard of M.P.E.P. § 2121.03.

Seed has now been collected from plants that were grown in quarantine, and the collected seed has been stored. The herbicide resistance characteristics of plants grown from that seed have not been tested by the inventor or his colleagues to date.

10. The Obviousness-Type Double Patenting Rejection

Claim 62 was rejected for obviousness-type double patenting over Claim 11 of the issued 6,943,280 patent.

Applicant has previously indicated a willingness to file a terminal disclaimer over the '280 patent, once the Office has indicated that this application is otherwise in condition for allowance.

The Office has stated that this ground of rejection cannot be held in abeyance. (June 23, 2006 Office Action, p. 6).

It would be premature to file a terminal disclaimer at this time. It is conceivable that the Claims might be amended further before this case is allowed, and it is possible that Applicant's willingness to file a terminal disclaimer could change in view of such amendments.

Applicant remains willing to file the proffered terminal disclaimer, once the Office has indicated that Claim 62 as currently written is otherwise in condition for allowance.

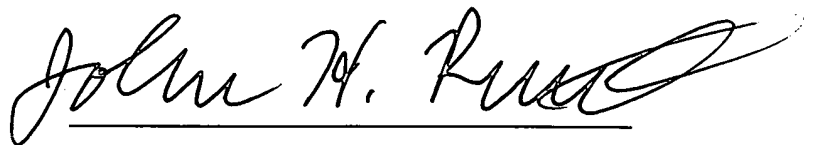
Conclusion

Allowance of all pending Claims at an early date is respectfully requested. The previously withdrawn Claims should now be rejoined, examined, and allowed.

In the alternative, should the Examiner identify any remaining issues, the Examiner is respectfully requested to contact the undersigned to schedule a telephone interview before further action is taken, to discuss whether it might be possible to resolve any such issues quickly, and to conclude the prosecution of this application.

Also, once the Examiner finds the case otherwise in condition for allowance, aside from the obviousness-type double-patenting rejection, the Examiner is respectfully requested to telephone the undersigned, so that the double-patenting issue might be resolved expeditiously (e.g., by fax) before a further action is mailed.

Respectfully submitted,

A handwritten signature in cursive script, reading "John H. Runnels", written in dark ink. The signature is fluid and stylized, with a long horizontal flourish extending to the right.

John H. Runnels
Taylor, Porter, Brooks & Phillips, L.L.P.
P.O. Box 2471
Baton Rouge, LA 70821
(225) 381-0257

Registration No. 33,451

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